

**AMENDMENTS TO THE DRAWINGS**

The attached sheets of drawings include changes to the following drawing sheets:

Sheet 1: Fig. 1,

Sheet 2: Fig. 1 (cont.)

These sheets replace the original drawing sheets 1 and 2.

Attachment: Replacement Sheets.

## **REMARKS/ARGUMENTS**

### **Amendments to the Specification**

Paragraphs and Tables: [006], [0011], [0014], [0018], [0019], [0022], [0023], [0027], [0028], [0029], [0030], [0031], [0032], [0035], [0050], ], [0055], Table 1, Table 2, Table 3, Table 4, [0067], [0073], [0084], [00114], [00115], [00116], [00117], [00121], [00122], and [00187] are amended to correct informalities.

Applicants made an inadvertent error that the numbering of the amino acid residues in the sequence is off by 12. Applicants correct this error throughout the disclosure. Support for the amendment may be found in the sequence listing of the full length human wide-type DPPIV accompanying the originally filed application. No new matter is added by the amendments.

Paragraph [00190] is amended to include a definition for "TCEP", paragraph [00191] is amended to include to a definition for "IMAC", and paragraph [00192] is amended to include a definition for "endo-F1 enzyme". These three terms are well known in the art; thus, no new matter is added by the amendments.

### **Amendments to the Drawing**

Figure 1 which is contained in Drawing Sheets 1 and 2 is amended to correct informalities. No new matter is added by the amendments. Applicants hereby provide the Replacement Drawing Sheets and a marked-up version which show the changes that were made.

### **Substitute Sequence Listing**

Applicants submit the enclosed Substitute Sequence Listing in order to amend the description of SEQ. I.D. No. 3 at line 221 so that the description of the N-terminal tag is consistent with Figure 3, as amended. No other amendments relative to the original sequence listing are made in the Substitute Sequence Listing.

Two copies of the Substitute Sequence Listing in written form are enclosed. A CD-R containing the Substitute Sequence Listing in computer readable form (CRF) is also enclosed.

Pursuant to 37 C.F.R. § 1.821(f) and (g), I hereby state that the information recorded in computer readable form on the enclosed CD-R is identical to the written Substitute Sequence Listing enclosed herein for the above-referenced application. I hereby further state that the submission, filed in accordance with 37 C.F.R. §1.821(g), herein does not include new matter.

### **Election/Restrictions**

The Examiner issued a telephonic restriction, where the claims were divided into Group I (claims 1-16, 22 and 23) and Group II (claims 17-21). The claims of Group I are drawn to an isolated protein and a crystalline composition of dipeptidyl peptidase IV, and the claims of Group II are drawn to a method of using the composition claimed in Group I.

Pursuant to 37 C.F.R. § 1.142 and in response to Examiner's telephonic restriction, Applicants elected Group I (claims 1-16, and 22-23) without traverse. By this amendment, claims 17-21 have been made dependent from claim 7.

Applicants reserve the right pursuant to 35 U.S.C. § 121 to file one or more divisional applications directed to the non-elected subject matter during the pendency of the present application.

### **Objection to the Disclosure Based on Informalities**

#### **(a) The phrase "residues 51-778 of SEQ. ID No. 1"**

Examiner objects to the phrase "residues 51-778 of SEQ. ID No. 1" because SEQ. ID No. 1 contains only 766 amino acid residues. Applicants note that an inadvertent error was made and that the phrase should read "residues 39-766 of SEQ. ID No. 1". Applicants amend the disclosure throughout to correct this error. Such error can be seen when comparing SEQ. ID No. 1 to the known sequence of human wild-type DPPIV. Hence, no new matter is added by this amendment.

#### **(b) The phrase "Endo-F1 enzyme treatment"**

Examiner objects that "endo-F1 enzyme treatment" on page 48, paragraph [00192] was not defined and it is not clear what kind of treatment it is. Applicant amends paragraph

[00192] to define Endo-F1 enzyme treatment as treatment by an endo-beta-N-acetyl glucosaminidase F. The enzyme cleaves all asparagine-linked hybrid or high mannose oligosaccharides. See excerpt from Product Listing of Glycotools (Exhibit A attached hereto). This treatment is well known in the art for studying the role of glycosylation in protein folding and activity. No new matter is added by the amendment.

(c) “IMAC”

Examiner objects that “IMAC” on page 48, paragraph [00191] is not defined at least once in the Specification. IMAC is the acronym for “immobilized metal affinity chromatography” purification. Applicants add this definition to paragraph [00191]. Given that this term is well known in the art, no new matter is added by the amendment.

(d) “TCEP”

Examiner objects that “TCEP” on page 49, paragraph [00190] is not defined anywhere in the Specification. TCEP is the acronym for “Tris(2-carboxyethyl)phosphine hydrochloride.” Applicants add this definition to paragraph [00190]. Given that this chemical is well known and commonly used in the art, no new matter is added by the amendment.

Applicants believe they have corrected each of the objections raised by the Examiner, and respectfully request the Examiner to withdraw the objections to the disclosure.

**Rejections under 35 USC §112, First Paragraph and 35 USC §102**

The Examiner rejects claims 1-13, 22 and 23 under 35 USC §112, First Paragraph on the ground that the claims, as presented, do not satisfy the written description or enablement requirements.

The Examiner also rejects claims 1-4, 7-10, and 14 under 35 USC §102(e) as being anticipated by U.S. publication US 2005/0260732 (the ‘732 application).

Applicants express with appreciation the Examiner’s indication that claims 15 and 16 would be allowable.

Applicants amend independent claims 1 and 7 so that such claims incorporate the limitations of claim 16 which the Examiner found to be allowable. Applicants amend dependent claims 8 and 18 to incorporate the limitations of claim 15 which the Examiner also found to be allowable.

In view of the above amendments to the claims, Applicants submit that pending claims 1, 4-8, 10-13, and 15-21, as amended, should overcome the Examiner's rejections under 35 USC §112, First Paragraph and 35 USC §102. Withdrawal of these rejections is therefore respectfully requested.

**Rejections under 35 USC §112, Second Paragraph**

Examiner rejects claims 1-14 under 35 USC §112, Second Paragraph as being indefinite.

Specifically, Examiner rejects claims 1-3, 7-9, and 14 based on the phrase "residues 51-778 of SEQ. ID No. 1". This rejection is rendered moot by Applicants' amendment of the claims to specify SEQ. ID No. 3.

The Examiner rejects claims 22 and 23 for failure to define "DPPIV" at least once in the claims. Claims 22 and 23 have been cancelled.

Withdrawal of the present rejections under 35 USC §112, Second Paragraph is respectfully requested in view of the amendments to the claims.

### CONCLUSION

In light of the amendments and remarks set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance.

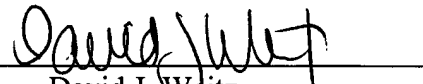
Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

TAKEDA SAN DIEGO, INC.

Dated: June 14, 2006

By:



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**Endo F1****Part number E-EF01****Endo F1, Endoglycosidase F1, endo-beta-N-acetylglucosaminidase F****Source** recombinant *Elizabethkingia meningosepticum* (was *Chryseobacterium meningosepti***EC 3.2.1.96****Contents**

60  $\mu$ l aliquot of enzyme (1 U) in 20 mM Tris-HCl, pH 7.5  
 5x Reaction Buffer - 250 mM sodium phosphate, pH 5.5

**Specific Activity** 16 U/mg**Activity** 17 U/ml**Molecular weight** 32,000 daltons**Suggested usage**

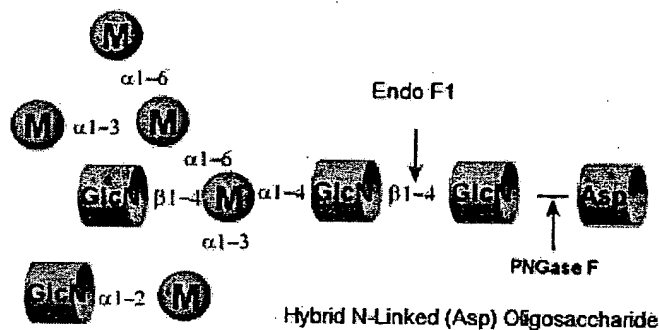
1. Add up to 200  $\mu$ g of glycoprotein to an Eppendorf tube. Adjust to 38  $\mu$ l final volume with de-
2. Add 10  $\mu$ l 5x Reaction Buffer 5.5
3. Add 2.0  $\mu$ l of Endo F1. Incubate 1 hour at 37°C.

**Specificity**

Cleaves all asparagine-linked hybrid or high mannose oligosaccharides

**Specific Activity**

Defined as the amount of enzyme required to catalyze the release of N-linked oligosaccharide micromole of denatured Ribonuclease B (RNase B) in 1 minute at 37°C, pH 5.5. Cleavage is r PAGE (cleaved RNase B migrates faster).

**Storage** Store enzyme at 4°C.

Selective release of hig  
 some hybrid type N-gly  
 peptides and proteins

E-EF01  
 recombinant *Elizabethk  
 meningosepticum* (was  
*Chryseobacterium men.*  
 View product document

Price: \$350.00